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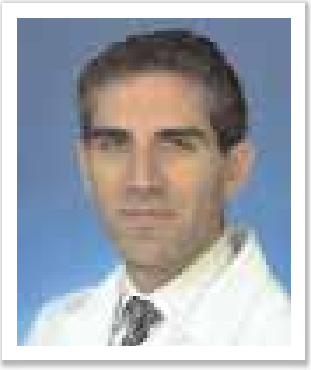
A discussion with a leading vascular surgeon on the current state of TEVAR/EVAR and how to prepare the physicians that will be performing these procedures in the future.

It has been a year since you wrote for *Endovascular Today* on "Future EVAR Devices." What developments have there been to address some of the issues you noted in your article, such as migration/fixation and metal/fabric fatigue?

The Aptus device (Aptus Endosystems, Inc., Sunnyvale, CA) has now completed enrollment of their clinical trial. They are waiting to collect the follow-up data. That device has a different fixation mechanism and a smaller delivery catheter profile. I did not write too much about that device's profile a year ago because it is a smaller issue for infrarenal aortic disease processes compared to thoracic processes. Cook Medical (Bloomington, IN) has recently announced a new trial that is going to evaluate their 16-F system (32-mm diameter) Low-Profile device. This next-generation device is going to significantly reduce the profile, which will help us treat a few more patients. The other concept behind the Cook Low Profile is that it is going to be MR compatible since it is nitinol based instead of stainless steel. All of the problems with endovascular aneurysm repair (EVAR) devices are slowly going to improve. Fatigue is a long-term issue, and we are not going to see that change acutely.



You are currently serving as lead investigator for the phase II Relay thoracic stent graft (Bolton Medical, Sunrise, FL) trial. What can you tell us about this device and the current trial?

Currently, there are three devices available in the US that are approved by the Food and Drug Administration. In a sense, they are not first-generation devices but "one-and-a-half–generation" devices because we have learned from the infrarenal aorta. If you look at those three devices, only one has tip capture on the proximal end of the device. The one that has tip capture does not have the largest diameter range of the devices available. In other words, it does not go up as high and does not go down as low in size as some of the others. Some of the advantages of the Bolton device are that it has tip capture, which helps with precise deployment, and it is available in additional sizes. It is similar to some of the other devices, but it is also a longer device, being marketed at 250 mm. We do not have a perfect device for thoracic disease or infrarenal disease that fits all patients. These improvements, however, are a step in the right direction. The perfect device would be a small-profile device that inserts easily, (from a thoracic standpoint) has a negligible stroke risk, is very flexible, does not migrate, and does not have any long-term fatigue problems.

The Relay phase II trial is approximately 50% enrolled, with about 60% men and 40% women, which is similar to other trials in the same area. Trials today are taking much longer to enroll because more people are doing thoracic procedures, and therefore, there are less training centers and trial sites to enroll patients.

Although thoracic endovascular aneurysm repair (TEVAR) is currently indicated only for use in treating descending thoracic aortic aneurysms, are there other indications for which endovascular repair is your treatment of choice?

Endovascular repair is my treatment of choice for the vast majority of patients that I see, but that reflects many different things. It reflects that the patients who are being sent to my practice are not good surgical candidates. The biggest thing we are going to see in the next several years is branched and fenestrated trials, as well as dissection trials. These type of devices are going to rapidly increase in use mainly because these types of patients do not have very good options at this point other than open surgery at most institutions. The trials will probably have rapid enrollment, and hopefully we will see additional indications for branched devices in thoracoabdominal aneurysms, fenestrated devices for

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pararenal aneurysms, and devices specifically designed for dissection treatment, as well thoracic aortic transections. How is TEVAR playing a role in treating patients with traumatic injuries, and what is the best device to use for dissections? I think that those questions will be answered in future clinical trials for thoracic disease.

What changes in technology will we see in the US over the next few years for the treatment of thoracic aortic pathologies?

We are going to see disease-specific devices. We may have one version of a device to treat transections, another modified version to treat aneurysms, and a third to treat dissections. Each may have different properties and configurations. For instance, the goal with a transection-designed device is to cover the transection so that it can heal, and migration is probably of no concern. A device implanted for aneurysmal disease, however, will need to exclude the aneurysm and avoid migration issues.

We will also see the profile size reduced. The most difficult problems to solve with thoracic disease are probably the branched aspect and stroke potential. When we perform procedures in this area, devices can be difficult to manipulate, and each additional maneuver increases the stroke risk. If we can keep the stroke risk down when the disease extends into the transverse arch, then we are going to see more branched devices come to the market more rapidly.

Do you believe that endovascular repair will ever be feasible in type A dissections?

Yes, that is a matter of modifying the device and the delivery system. I think there are some minor issues to address in terms of the procedural steps, such as arresting the heart, making sure you do not cause problems with the coronary arteries, etc. To date, this type of device has not received a high enough priority from the device manufacturers. This is surprising because there are more type A dissections than there are type B dissections. Maybe the manufacturers were concerned about whether imaging and technology had advanced enough in order to accomplish good outcomes. I believe that it is something that will happen; it is just a matter of time.

What are some of the vascular studies currently ongoing at the University of North Carolina, either single-center or as part of a multicenter trial?

As a result of being one of the major aortic centers in the Southeast, we have been asked to participate in numerous trials. These include a fenestrated trial for pararenal aneurysms and hopefully branched trials in the near future. We have participated in the Aptus AAA STAPLE trial and expect that this trial will have continued access until a decision from the Food and Drug Administration occurs. We are also involved with several trials for thoracic devices for the treatment of dissections and traumatic injuries. Additionally, our group is involved in trials for vascular problems other than aortic disease, which include evaluating new vena cava filters and endothelial growth factors to improve the results for revascularization of the lower extremities. We are also looking at new agents to stop periprocedural bleeding (ie, thrombin-type agents). Those are some of the major areas in which we are doing trials, but as always, there is a multitude of trials at the University of North Carolina.

I think this really reflects what vascular specialists do. I call ourselves *vascular specialists* because we medically manage the patient, we look at the patient from a surgical standpoint, and we can take care of the patient endovascularly. In our armamentarium lie all these capabilities. We do not just perform one technique, and we manage the patients all individually, choosing the best therapy based upon the risks and benefits of all their options.

How will the training of the future vascular specialist occur?

We are doing all of these endovascular procedures for aortic disease and fewer open procedures. How are we going to train the young physician to operate when the patient needs an operation in the future? That training is becoming harder and harder to do. First, the physicians that come to us from general surgery programs are performing fewer operations in those programs because of laparoscopic work and thus have less surgical experience. We are therefore trying to develop a surgical simulator for open surgical procedures, but we are also still doing a fair number of hybrid procedures, which means the trainees learn operative skills and decision making. They learn the planning of the procedures, and they learn the thought process. It is not always about putting the suture through the large anastomosis. That is relatively easy to do when compared to the aforementioned items.

If a physician is in a small training program that does not have a major aortic concentration, it may be important that the physician do an additional training year at a program that specializes in this area to obtain the additional skills mentioned. There is no substitute for experience, and the US is becoming more and more focused on the quality of care and outcomes. ■